Smith & Nephew Pty Ltd – "*Bioinductive Implant with Arthroscopic Delivery System - Multi-purpose surgical mesh, collagen*" (ARTG 384118)

Therapeutic Goods Act 1989

Approval under section 42DF for use of restricted representations by Smith & Nephew Pty Ltd

I, Michael Shum, as a delegate of the Secretary to the Department of Health, Disability and Ageing, on receipt of an application from Smith & Nephew Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations described in paragraph (**A**), for use in advertisements for the product identified in paragraph **(B)**, when the statements identified in paragraph **(C)** are prominently displayed or communicated[1] in the advertisement in which the restricted representations are used (including on the label and packaging of the goods), subject to the conditions identified in paragraph **(D)**.

(A)

1. Representations to the effect that Regeneten is a surgical implant that can be used to manage and protect rotator cuff tendon injuries in some patients.
2. Representations to the effect that, when used for rotator cuff tendon injuries, Regeneten is placed directly on the injured tendon, either:
   a. without any surgical repair to the tendon; or
   b. as part of surgery in which the injured tendon is re-attached to the bone.
3. Representations to the effect that, by supporting the body to grow new tendon-like tissue at the rotator cuff tendon injury, Regeneten can help reduce the risk of the rotator cuff tendon re-tearing following corrective surgery.
   a. When used in conjunction with the representation outlined in paragraph 4.
4. Representations to the effect that Regeneten provides a collagen scaffold that enables/supports the body to grow new tendon-like tissue to repair the damaged tendon in the rotator cuff, before being absorbed by the body after around 6 months.
   a. When used in conjunction with the representation outlined in paragraph 2.

[1] ***prominently displayed or communicated***, in relation to a statement in an advertisement, means:
(a) either:
   (i) for a visual statement—easily read from a reasonable viewing distance for the particular media type in the context in which the advertisement is intended to be viewed; or
   (ii) for a spoken statement—able to be clearly heard and understood; and
(b) repeated as often as necessary to be noticed by a viewer or listener

5. Representations in Regeneten advertising that refer to rotator cuff tendon injuries, tendinosis and tendonitis to the effect of providing accurate, balanced, contemporary and non-promotional information, the purpose of which is to inform consumers, in plain language, about:
    a. the anatomy of the rotator cuff, with a focus on the tendons and how they contribute to the shoulder joint function and movement;
    b. how tears/injuries to the rotator cuff tendons can occur and their incidence or prevalence relevant to the Australian population;
    c. the spectrum of rotator cuff injuries, including how minor injuries (tendinosis) can progress to more serious inflammation (tendonitis) through to partial and full thickness tears;
    d. how rotator cuff tears/injuries are diagnosed;
    e. the symptomology of rotator cuff tendon injuries and how a person can be affected in relation to movement and activities;
    f. when to seek medical advice for rotator cuff tendon injuries;
    g. conservative (non-surgical) treatment, in a high-level capacity, and its role in rotator cuff tendon injury recovery and as a prerequisite to surgery; and
    h. the surgical treatments that may be used to assist in repairing rotator cuff tendon injury, including those that can be used in conjunction with Regeneten.
6. Representations that refer to rotator cuff tendon tears/injuries, tendinosis, tendonitis and infections to the effect of providing accurate, balanced, and contemporary information, the purpose of which is to inform consumers, in plain language, about:
    a. the constitution, size, age, bioinductive features and other physical characteristics of Regeneten implants;
    b. how Regeneten is inserted and affixed to assist rotator cuff tendon tears, including how it can augment surgical repair of the tendon/s;
    c. how the Regeneten implant is eventually absorbed by the body;
    d. contraindications for the use of Regeneten (e.g. infections); and
    e. post-operative care and rehabilitation following implantation.

together, (the **Approved Representations**).

(B)

- Bioinductive Implant with Arthroscopic Delivery System - Multi-purpose surgical mesh, collagen (ARTG 384118).

(C)

- Speak to your doctor about whether Regeneten may be suitable for you.
- Your orthopaedic surgeon/doctor will decide whether Regeneten is suitable for you, based on your situation, including the nature of your rotator cuff injury/tear.
- Surgery is required to use this product. Any surgical procedure carries risk.

(D)

- Representations in advertisements about the incidence or prevalence of rotator cuff tendon injury, must reflect the body of contemporary knowledge about rotator cuff tendon injury and be relevant to the Australian population.
- References to ‘infections’, are only to be used as a contraindication to or consequence of rotator cuff surgery when using the Device.

- Representations must only reflect the device and its related surgical procedures available and supplied in Australia.

Dated this 15th day of August 25

Signed electronically

Michael Shum

Delegate of the Secretary to the Department of Health, Disability and Ageing

Education Policy and Guidance Section

Regulatory Compliance Branch